UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MINNESOTA

AZURITY PHARMACEUTICALS, INC., Plaintiff, v. ANI PHARMACEUTICALS, INC., Defendant.	Case No.: _____ **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Azurity Pharmaceuticals, Inc. ("Azurity"), brings this action for patent infringement against Defendant ANI Pharmaceuticals, Inc. ("ANI"), and alleges as follows:

The Parties

1. Azurity is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 841 Woburn St, Wilmington, MA 01887.

2. Azurity was previously known as CutisPharma, Inc. and officially changed its name to Azurity Pharmaceuticals, Inc. on or around February 3, 2020.

3. Azurity is a specialty pharmaceutical company focused on making safe, high-quality products for patients who require formulations of drugs other than what is commonly commercially available (such as tablets and capsules). Azurity's products have benefitted millions of patients who are unable to swallow conventional oral dosage

forms such as tablets and capsules and whose needs are not served by other commercially available therapies.

4. On information and belief, ANI is a Delaware corporation, having a principal place of business at 210 Main Street West, Baudette, MN 56623.

Jurisdiction and Venue

5. This is an action for patent infringement arising under the patent laws of the United States of America, Title 35 of the United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over ANI because its principal place of business is located in this judicial district and because, on information and belief, ANI has committed acts within Minnesota giving rise to this action and/or has established minimum contacts with Minnesota such that the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice.

7. On information and belief, ANI regularly and continuously transacts business in Minnesota, including by directly or indirectly developing, manufacturing, marketing, and selling generic pharmaceutical products in Minnesota, including ANI's "Vancomycin Hydrochloride for Oral Solution" ("Accused Product").

8. On information and belief, ANI derives substantial revenue from the sale of products, including the Accused Product, in Minnesota and has availed itself of the privilege of conducting business within Minnesota.

9. For example, the label for the Accused Product states: "Manufactured by: ANI Pharmaceuticals, Inc.[,] Baudette, MN 56623." Ex. 1 at 4.

10. Further, the Accused Product is marketed on a website "intended for U.S. Healthcare Professionals," which claims the Accused Product is "[n]ow available." Ex. 2 (accessed Mar. 7, 2021).

11. Venue with respect to ANI is proper under 28 U.S.C. §§ 1391 and 1400(b) at least because ANI has committed acts of infringement in this judicial district and has a regular and established place of business in this judicial district.

Azurity's FIRVANQ® Product

12. *Clostridium difficile* ("*C. diff.*") is the most common cause of healthcare-associated infection in United States hospitals, with up to ~500,000 cases and ~29,000 deaths occurring in 1 year in the United States. *C. diff.* infection-related costs have been estimated at $4.8 billion for acute care facilities alone. Oral vancomycin is recommended as a first-line treatment in cases of *C. diff.* infection.

13. Azurity's FIRVANQ® product is an FDA-approved antibacterial indicated in adults and pediatric patients less than 18 years of age for the treatment of *C. diff.*-associated diarrhea. FIRVANQ® is also indicated for the treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains).

14. Azurity holds New Drug Application "NDA" No. 208910, directed to its FIRVANQ® product and approved by the United States Food and Drug Administration ("FDA") in January 2018.

Patent-In-Suit

15. United States Patent No. 10,688,046 ("'046 patent"), entitled "Composition and Method for Vancomycin Oral Liquid," was duly and legally issued on June 23, 2020,

to CutisPharma, Inc. (Azurity's previous name) as assignee of the inventors, Indu Muni, Peter Mione, Anisa Gandhi, and Cristina LeChiara. A true and correct copy of the '046 patent is attached to this Complaint as Exhibit 3.

16. Azurity is the sole owner of the entire right, title, and interest in and to the '046 patent, including the right to sue and to recover for any and all infringement thereof.

17. The '046 patent is valid and enforceable.

ANI's Accused Product

18. On information and belief, ANI markets, makes, uses, sells, offers to sell, imports into the U.S., and/or induces or contributes to the use of ANI's generic "Vancomycin Hydrochloride for Oral Solution" ("Accused Product") in the United States.

19. According to the label for the Accused Product, "[e]ach 5 mL of reconstituted solution contains vancomycin hydrochloride equivalent to 250 mg (0.17 mmol) vancomycin." Ex. 1 at 1.

20. The label for the Accused Product lists the following "[i]nactive ingredients: citric acid anhydrous, sodium benzoate, sucralose, and mixed berry flavor." *Id*.

21. The label further states: "Vancomycin Hydrochloride for Oral Solution is administered orally for treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains) and antibiotic-associated pseudomembranous colitis caused by *C. difficile*. Parenteral administration of vancomycin is not effective for

the above indications; therefore, Vancomycin Hydrochloride for Oral Solution must be given orally for these infections." *Id*. at 1-2.

22. On information and belief, ANI submitted a supplemental abbreviated new drug application ("sANDA") directed to the Accused Product on or around September 27, 2018—eight months after FDA approval of Azurity's FIRVANQ® product.

23. On information and belief, ANI identified the following components to the FDA as comprising the "Final Reconstituted Formulation" of the Accused Product: vancomycin HCl, citric acid anhydrous, mixed berry flavor, sodium benzoate, sucralose, and water. Ex. 4 at 137.

ANI's Infringing Activities

24. The Accused Product and use thereof is covered by one or more claims of the '046 patent.

25. Provided here as a representative claim for exemplary purposes, claim 1 of the '046 patent recites:

A non-sterile stable liquid formulation formulated for oral administration, consisting of:

(a) 0.1-0.4% w/v anhydrous citric acid,

(b) water,

(c) a sweetener that is sucralose,

(d) 0.02-0.08% w/v sodium benzoate,

(e) 10-60 mg/ml vancomycin hydrochloride, and

(f) flavoring agent,

wherein the non-sterile stable liquid formulation is homogenous and stable for at least 2 weeks at ambient and refrigerated temperature and has a pH of 2.5-4.5.

26. Likewise, provided here as a representative claim for exemplary purposes, claim 8 of the ’046 patent recites:

A method of treating *Clostridium difficile* pseudomembranous colitis or Staphylococcal enterocolitis in a subject comprising administering a vancomycin oral liquid composition to the subject in a therapeutically effective amount, wherein the vancomycin oral liquid composition consists of:

(a) 0.1-0.4% w/v citric acid,

(b) water,

(c) a sweetener that is sucralose,

(d) 0.02-0.08% w/v sodium benzoate,

(e) 20-60 mg/ml vancomycin hydrochloride, and

(f) flavoring agent,

wherein the vancomycin oral liquid composition is homogenous and stable for at least 2 weeks at ambient and refrigerated temperature and has a pH of 2.5-4.5.

27. On information and belief, ANI markets, makes, uses, sells, offers to sell, and/or induces or contributes to the use of the Accused Product in a manner that infringes one or more claims of the ’046 patent.

28. Typical use of the Accused Product involves reconstitution with water, and the label which ANI distributes with the Accused Product instructs reconstitution with water. Ex. 1 at 1, 3-4. For example, the label for the Accused Product states, in part:

PREPARATION AND STABILITY

Mix the contents of the bottle with water as directed below. When reconstituted, each 5 mL contains approximately 250 mg of vancomycin. These mixtures may be kept for two weeks in a refrigerator

without significant loss of potency.

Directions for mixing Vancomycin Hydrochloride for Oral Solution USP:

80 mL – Slowly add 80 mL water and shake vigorously.

150 mL – Slowly add 150 mL water and shake vigorously.

300 mL – Slowly add 300 mL water and shake vigorously.

29. On information and belief, ANI or its agents have reconstituted the Accused Product with water.

30. On information and belief, persons, including healthcare providers, pharmacists, and/or end users have reconstituted the Accused Product with water in compliance with the instructions ANI provides in the labeling for the Accused Product.

31. Upon reconstitution, the Accused Product contains approximately 50 mg/ml vancomycin, water, citric acid, sodium benzoate, sucralose, and mixed berry flavor. *Id*. at 4 at 137.

32. On information and belief, upon reconstitution, the Accused Product contains 0.1-0.4% w/v anhydrous citric acid and 0.02-0.08% w/v sodium benzoate or an equivalent thereof. On information and belief, when prepared in compliance with the instructions ANI provides in the labeling for the Accused Product, the formulation is homogenous and stable for at least 2 weeks at ambient and refrigerated temperature and has a pH of 2.5-4.5.

33. On information and belief, ANI's ongoing business operations include analysis of the patent landscape relevant to ANI's current and contemplated products. *See, e.g.*, Ex. 5 at 36 ("We consider a variety of criteria in determining which products to develop, all of which influence the level of competition upon product launch. These criteria include: . . . ***Patent Status.***").

34. On information and belief, ANI was aware of Azurity's FIRVANQ® product when it sought FDA approval for the Accused Product. Ex. 4 at 53, 62, 64, 123.

35. Pursuant to 21 U.S.C. § 355(b)(1), the '046 patent was listed on July 10, 2020, in the FDA publication titled, *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book"), as covering Azurity's FIRVANQ® product.

36. The '046 patent is and has been publicly available since its June 23, 2020 date of issue.

37. On information and belief, ANI had knowledge of the existence of the '046 patent prior to the filing of this lawsuit.

38. On information and belief, ANI knows or should have known that the Accused Product would be used in a manner that infringes the '046 patent.

Cause of Action:
Infringement of the '046 Patent

39. Azurity repeats and incorporates by reference the allegations of paragraphs 1-38, as though fully set forth herein.

40. On information and belief, ANI or its agents has made or used the Accused Product to practice, *inter alia*, claim 1 of the '046 patent in the United States. Accordingly, ANI has directly infringed and is directly infringing, literally and/or under the doctrine of equivalents, the '046 patent under 35 U.S.C. § 271(a).

41. On information and belief, ANI has encouraged others (e.g., pharmacists, healthcare providers, and end-users) to use the Accused Product in a manner that infringes one or more claims of the '046 patent while having knowledge of the '046 patent and while knowing that the use it encourages constitutes direct infringement of one or more claims of the '046 patent, either literally or under the doctrine of equivalents. On information and belief, ANI's encouragement has led to the Accused Product being used in a manner that directly infringes, either literally or under the doctrine of equivalents, one or more claims of the '046 patent. Accordingly, ANI is liable for induced infringement of one or more claims of the '046 patent under 35 U.S.C. § 271(b).

42. On information and belief, in addition to making and providing the Accused Product, ANI induces infringement by others by providing a label with the Accused Product instructing others to use the Accused Product in a manner that infringes, either literally or under the doctrine of equivalents, one or more claims of the '046 patent.

43. On information and belief, the reconstitution of the Accused Product (by a pharmacist, healthcare provider, or other person(s)) and subsequent use thereof in accordance with the instructions in ANI's labeling for the Accused Product has resulted in direct infringement, either literally or under the doctrine of equivalents, of one or more claims the '046 patent.

44. On information and belief, the Accused Product is designed to be used in a manner that directly infringes, either literally or under the doctrine of equivalents, one or more claims of the ’046 patent.

45. On information and belief, the Accused Product does not have any substantial use that would not infringe the claims of the ’046 patent, and the Accused Product constitutes a material part of the subject matter claimed in the ’046 patent. Accordingly, ANI is liable for contributory infringement of one or more claims of the ’046 patent under 35 U.S.C. § 271(c).

46. The commercial manufacture, use, offer for sale, sale, and/or importation of the Accused Product in violation of Azurity’s patent rights has caused and will continue to cause substantial and irreparable harm to Azurity for which damages are inadequate.

Prayer for Relief

Azurity respectfully requests judgment and relief as follows:

a) A judgment that ANI has infringed, either literally or under the doctrine of equivalents, one or more claims of the ’046 patent under 35 U.S.C. § 271(a), (b), and (c);

b) A finding that the claims of the ’046 patent are valid and enforceable;

c) A judgment that ANI’s infringement was willful;

d) Injunctive relief prohibiting ANI and its officers, partners, employees, agents, parents, subsidiaries, attorneys, and anyone acting in concert or participation with ANI from further infringement of the ’046 patent, in accordance with 35 U.S.C. § 283;

e) Damages adequate to compensate Azurity for ANI's infringement, in accordance with § 284, including lost profits and/or a reasonable royalty, together with interest thereon;

f) Treble damages and/or exemplary damages for ANI's willful infringement under 35 U.S.C. § 284;

g) A finding that this is an exceptional case under 35 U.S.C. § 285, and that Azurity be awarded reasonable attorneys' fees and costs; and

h) An award of any such other and further relief as the Court may deem just and proper.

Jury Demand

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Azurity demands a jury trial on all issues so triable.

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March 24, 2021